Towards a more open debate about values in decision-making on agricultural biotechnology

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ABSTRACT

Regulatory decision-making over the use of products of new technology claims to be based on science-based risk assessment. In Europe, decision-making about the cultivation of genetically modified (GM) plants is blocked supposedly because of scientific uncertainty about risks to the environment. However, disagreement about risk is primarily a dispute over normative values, which is not resolvable through natural sciences. Natural sciences may improve the quality and relevance of the scientific information used to support environmental risk assessments and make scientific uncertainties explicit, but offer little to resolve differences about values. Decisions about cultivating GM plants will not necessarily be eased by performing more research to reduce scientific uncertainty in environmental risk assessments, but by clarifying the debate over values. We suggest several approaches to reveal values in decision-making: (1) clarifying policy objectives; (2) determining what constitutes environmental harm; (3) making explicit the factual and normative premises on which risk assessments are based; (4) better demarcating environmental risk assessment studies from ecological research; (5) weighing the potential for environmental benefits (i.e., opportunities) as well as the potential for environmental harms (i.e., risks); and (6) expanding participation in the risk governance of GM plants. Recognising and openly debating differences about values will not remove controversy about the cultivation of GM plants. However, by revealing what is truly in dispute, debates about values will clarify decision-making criteria.

KEYWORDS

Controversy, environmental risk assessment, genetically modified plants, governance, values

INTRODUCTION

In most jurisdictions, the commercial growing and use of genetically modified (GM) plants is regulated by risk-based legislation (Ramessar et al. 2009). Ideally, the role of risk assessors is to valuate the probability and seriousness of harm to the environment and to human and animal health from a course of action, such as cultivating or consuming a GM plant. Assessments follow the scientific method for the identification, gathering and interpretation of data. The decision on the level of acceptable risk, and thus whether a GM plant may be commercialised, is taken by risk managers who weigh policy options to accept, minimise or reduce the characterised risks. Additional measures for prevention and control of specific risks may also be required. Judging the acceptability of risks involves value judgements, including socio-ethical and economic considerations, and thus imposes a political overlay on scientific evaluation (Johnson et al. 2007; Collins et al. 2010). Risk communication then involves dialogue between risk assessors, risk managers and other interested parties, including the explanation of risk assessment conclusions and the basis upon which regulatory decisions were made. Although interrelated, scientific risk assessment, risk management and risk communication fulfil different roles in, and contribute differently to, decision-making. Scientific information in risk assessment can lend credibility to regulatory decisions but it does not dictate decisions because effective decision-making is not based solely on scientific evidence (Lawton 2007).

Political judgements on the acceptability of growing GM plants and admitting them to the food chain vary widely across different jurisdictions, most notably between the EU and the USA (Tait 2008). In Europe, the environmental risks of GM plants have been hotly debated. Morris and Spillane (2010) have argued that the EU's regulatory system for the cultivation of GM plants is unsustainable in its present form, given that 12 years after the implementation of the revised frame in 2001, only one GM plant (amflora potato) has been approved for cultivation (Nature 2007; Raybould and Poppy 2012).

Several EU Member States regularly raise safety objections during regulatory review, or invoke safeguard clauses to provisionally restrict or prohibit the marketing of previously approved GM plants on their territory, or both (Ricroch et al. 2010; Sabalza et al. 2011; Devos et al. 2012; Kuntz et al. 2013). By law, the Member State must provide scientific information to justify its objection. In each case that it has evaluated an objection, the European Food Safety Authority (EFSA) concluded that no new scientific evidence had been presented that would invalidate its previous risk assessment conclusions or risk management recommendations.

Given similar scientific information and adoption of the scientific method in risk assessment, one would expect similar outcomes in terms of risks and their acceptability to the relevant authorities in different jurisdictions. However, in Europe, the invocation of safeguard clauses demonstrates how a value-based political overlay can be applied to scientific information (Hilbeck et al. 2011; Kuntz 2012; Raybould 2013), leading to divergent estimates of risk and risk management decisions. Decisions on whether to authorise a GM plant will thus depend on several things: the interpretation of the scientific information (Wickson and Wynne 2012a,b; Romeis et al. 2013); views of what constitutes environmental harm (Sanvido et al. 2012); visions of a desirable agricultural future (Marsden 2008); institutional cultures on risk management (Montpetit and Rouillard 2008); precautionary approaches taken (Mayer and Stirling 2002); and responses to political pressures and public perception (Lawton 2007; Sinha 2009).

In Europe, final risk management decisions tend to be determined by political judgements that are influenced mainly by value-based opinions held by environmental non-government organisations (Tait 2009). However, the value-driven nature of such influences is often difficult to verify, given that there are strong pressures within the regulatory system itself to express concerns in terms of factual evidence of specific risks (Tait 2001). Although natural sciences lie at the centre of the debate, scientific facts can offer little to resolve such value differences in environmental controversies, and may further polarise opinion (Sunstein 2009). Scientific information can often be interpreted in different ways, providing opportunities to reinforce value-based disputes (Sarewitz 2004). Advocates arguing from a value-based position can usually find facts, theories and hypotheses consistent with their own normative framework (Tait 2001). In consequence, both sides in a dispute about risks may argue on a basis of apparently ‘sound science’, as is often the case with GM plants. However, one characteristic of value- or ideologically-based advocacy is a lack of concern for the quality of the scientific evidence used to support conclusions about risks (Tait 2009). In such circumstances, the scientific debate itself conceals the value preferences behind pseudo-technical arguments.

Improved decision-making on GM plant development in Europe will require clarification of the nature of current disagreements on the environmental risks of GM plants. Performing more research to generate additional scientific information and increase confidence in environmental risk assessments is0 unlikely to solve the problem. Instead, risk managers need to recognise the political nature of the values underlying the conflict and to bring them to the foreground of the decision-making process, enabling a more broadly based democratic approach to decision making in Europe (Collins 2010).

Here, we explore means to reveal hidden value differences underlying the controversy about GM plants, so that risk managers can appropriately take the results of environmental risk assessments into account, openly recognise and discuss value differences, explore their implications for society, and take suitable decisions without hiding behind the scientific controversy. We illustrate points with examples from EU regulatory decision-making about the import or cultivation of certain GM plants. However, the problems we analyse are not unique to the EU or to GM plants.

MEANS TO REVEAL NORMATIVE VALUES IN DECISION-MAKING

Clarifying policy objectives

Key to the successful operation of regulatory decision-making in the context of risk-based legislation is the relationship between legal policy objectives and risk assessment (Collins 2010). Risk assessors use scientific information to test hypotheses about the likelihood and seriousness of harmful effects that may occur following a course of action, such as cultivating or consuming a particular GM plant (Raybould 2006). This information may exist prior to the risk assessment, or may be acquired by new studies. It is vital that the assessment focuses on predicting harmful effects, because it is unnecessary and infeasible to attempt to characterise all possible effects that may result from an action (Raybould 2010).

What effects are regarded as harmful, however, cannot be determined by scientific analysis of information. Risk managers must interpret the objectives of policy and regulations to define harm. If harm is not defined, risk assessors face an extremely difficult or impossible task because there are no criteria to determine whether certain potential effects of an action are relevant to the risk assessment. The absence of definitions of harm is a symptom of what Evans et al. (2006) called the risk assessment – policy gap: the lack of clear policy objectives from which risk managers can set decision-making criteria that can focus risk assessment on certain effects and exclude others as irrelevant (Sarewitz 2004). Natural sciences can investigate the consequences of actions, but cannot reveal normative truths about what society must do and which actions should be taken.

Determining what constitutes environmental harm

At the start of the risk analysis, risk managers must decide which kinds and levels of change are relevant and represent harmful effects (Sanvido et al. 2012). This is a necessary condition for the risk assessment, as the determination of environmental harm is subjective and will differ depending on perspective. Risk managers can only use natural sciences to determine whether a

certain action is good or bad once ‘‘good’’ and ‘‘bad’’ have been defined. Consequently, risk managers must be explicit about which environmental resources are to be protected, where and over what time period they must be protected, and what level of change is found acceptable. This involves the political process of setting the pertinent baselines for comparison and thresholds when performing environmental risk assessments. These normative choices define the framework in which risk assessors have to operate (Winickoff et al. 2005). These normative choices are claimed, in the context of GM plant developments in Europe, to be reflections of what society considers important and therefore democratic, although in practice they are an example of the domination of decision-making by an unrepresentative minority (Tait 2009). As indicated by the continuing debate on the risks of GM plants, consensus on definitions of environmental harm (i.e., criteria on which a judgment or a decision may be based) is presently lacking (Sanvido et al. 2012; Raybould 2013).

Establishing what is to be regarded as environmental harm is a complex process of analysing and implementing policy objectives. It requires that risk managers define what deserves protection and what level of change is to be regarded as harmful based on existing legislation and societal aspirations. The necessary normative choices are usually set in broad terms by existing environmental and agricultural policies that define protection goals, appropriate baselines to compare the impacts of GM plants to existing cropping systems, as well as thresholds to be applied.

Most legal frameworks require the protection of human and animal health and the environment (or more specifically of biodiversity) from harm. It follows that the first step in defining harm should be the characterisation of protection goals. In a second step, one must derive scientifically measurable entities on the basis of protection goals. Protection goals are often too vague to be scientifically useful for risk assessment and regulatory decision-making (Evans et al. 2006; Raybould 2012). To be useful, it is important that these general and broadly formulated protection goals are translated into concise and concrete measurable endpoints and scientifically testable hypotheses (Garcia-Alonso and Raybould 2013; Herman et al. 2013). Such endpoints are required for regulatory decision-making because they specify what is to be protected. Furthermore, they allow quantifiable predictions of the probability and seriousness of harmful effects during risk assessment. Generic conceptual frameworks, relying on the ecosystem services concept (Nienstedt et al. 2012), have proven suitable to make protection goals operational for use in the environmental risk assessment of GM plants (Sanvido et al. 2012; Garcia-Alonso and Raybould 2013).

Making explicit the factual and normative premises on which risk assessments are based

Uncertainty is often cited as the reason why decision-making can be protracted and contentious (Stirling 2007). Environmental risk assessments themselves and scientific information used in support of the risk assessment may be complex, difficult to interpret and overwhelm risk managers. This may be attributed to uncertainties inherent to scientific discovery, variability, as well as differences in the scientific quality and validity of the presented information (Gray 2004). The scientific community and peer-reviewed journals themselves have been accused of fuelling misinterpretations and misinformation outside the scientific community by publishing flawed and misleading publications (Miller et al. 2008; Waltz 2009; Rauschen 2010; Arjó et al. 2013; Romeis et al. 2013). One might therefore argue that the current debate on GM plants is related to a growing awareness of risk managers of the limitations of environmental risk assessments, which ultimately impede them to take definitive risk conclusions knowing that they cannot predict the consequences of decisions with sufficient certainty.

Performing more research is often prescribed as the solution to increase confidence in environmental risk assessments, thereby improving trust in decision-making (Jaffe 2006). However, new scientific information quite often reveals previously unknown complexities, increasing the sense of uncertainty and highlighting the differences between competing perspectives (Sarewitz 2007). Although substantial scientific information on the environmental and agricultural impacts of the currently commercialised GM plants is available today (reviewed by Sanvido et al. 2007; Lemaux 2009; Carpenter 2011), it has not resulted in shorter decision times or reduced controversy over GM plant market registration applications for cultivation in Europe (Raybould 2010; Raybould and Poppy 2012). Therefore, it seems that the debate about the risks and acceptability of GM plants is less caused by a lack of peer-reviewed scientific information, but more by an excess of scientific information that supplies contesting parties with their own body of relevant 'facts' (Sarewitz 2004). In this debate, scientific uncertainty often becomes a ready-made substitute for what is in reality a difficult political decision.

The interpretation of scientific information, as well as the significance of uncertainty are and will inevitably remain an issue of debate (Sinha 2009). It is therefore important that the premises underlying risk assessments and the nature and magnitude of uncertainties associated with the characterised risks are made explicit, so that risk managers can appropriately take the results of environmental risk assessments into account (Jasanoff 2003; Nowotny 2003). Risk assessments should specify the types of uncertainty encountered and indicate their relative importance and

influence on the result of the risk assessment (Hayes 2011). Transparency is also required about the choice of relevant hypotheses to be tested, the baselines for comparison, thresholds, methodologies and working assumptions used when conducting environmental risk assessments. Ideally, these normative choices should be made by risk managers prior to risk assessments, as they define the framework in which risk assessors have to operate. In reality, however, such choices are not necessarily defined or set choices are under dispute. Furthermore, the separation of risk management and risk assessment may be difficult to achieve. It has been argued that risk assessors may implicitly make normative choices, and that these choices become embodied in apparently purely scientific considerations (Wickson and Wynne 2012a,b). On the other hand, it is clear that challenges to the scientific evidence and its validity, along with an over-emphasis on scientific uncertainty, can also be used as political weapons of argument designed, for example, to delay or prevent authorisation of GM plants (Tait 2001).

To ensure that risk managers can appropriately consider how scientific information to support the risk assessment has been evaluated and framed, normative elements that may have contributed to the arrival at alternative assessments of scientific information, or led to the creation of alternative framings for risk assessment, should be made explicit. In this process, it is vital that the scientific quality and validity of information for risk assessments are scrutinised in a sound, consistent and transparent manner, particularly when the new information challenges an accepted body of knowledge Hilbeck et al. 2012; Romeis et al. 2013). Scrutiny enables risk 212 managers to determine how much reliance can be placed on each piece of information, and to justify why only those scientific facts meeting previously defined quality criteria are further considered in risk assessments (OGTR 2009). Such transparency may help to guard against the wilful misinterpretation or selective use of the scientific information to support existing positions (Herrick and Jamieson 2001; Miller et al. 2008; Arjó et al. 2013; Romeis et al. 2013). Good experimental design and statistical practices are important tools for ensuring objective and transparent data analysis (Perry et al. 2009; Romeis et al. 2011; Semenov et al. 2013).

Demarcating environmental risk assessment studies from ecological research

Not all information on the ecology GM plants available in the scientific literature is equally relevant to their environmental risk assessment (Craig et al. 2008). This is because ecological research and environmental risk assessment differ in the sources of problems, the nature of hypotheses under test, and even the methods for testing hypotheses (Hill and Sendashonga 2003; Raybould 2006, 2007, 2010, 2011). As an example, various studies assessing the impact

of GM plants have postulated risks when all they have done is characterised a hazard associated with the use of a GM plant, an exposure to the GM plant without demonstrating whether this exposure is hazardous, or simply a property of the GM plant unrelated to hazard or exposure to anything of value (reviewed by Johnson et al. 2007). Such studies rarely link hazard to exposure, and in effect confuse hazard or exposure with risk. Furthermore, often the concept of statistical significance is confused with biological relevance (EFSA 2011). Statistically significant differences may point to biological changes caused by the genetic modification, but these may or may not be meaningful in terms of harm to humans, animals and the environment. It is therefore critical to not only evaluate the scientific quality and validity of studies used to inform environmental risk assessments, but also to consider their relevance to risk assessment.

Johnson et al. (2007) considered it irresponsible to claim that an ecological study has relevance to the risk assessment without explaining how. A minimum requirement should be a conceptual model that links the data to a possible adverse effect on something of value. Johnson et al. (2007) further argued that if data claim to assess risk, but do not, they merely increase unease about environmental risks of GM plants, and increase rather than decrease uncertainty. Therefore, it has been suggested that uncertainty in regulatory-decision making about GM plants may be reduced more effectively by clarifying the purpose and structure of the environmental risk assessment than by performing further ecological research (Raybould 2010). This clarification will underpin the usefulness of new scientific information to risk assessments.

Problem formulation has proven adequate to maximise the usefulness of environmental risk assessment studies for decision-making, as it enables a structured, logical approach to identifying harmful effects requiring characterisation, while excluding non-harmful effects as irrelevant Raybould 2006; Wolt et al. 2010; Gray 2012). It involves several elements: 247 the identification of characteristics of the GM plant capable of causing potential adverse effects (hazards) and pathways of exposure through which the GM plant may adversely affect human and animal health or the environment; the definition of assessment endpoints, which are explicit and unambiguous targets for protection extracted from legislation and public policy goals; and outlining specific hypotheses to guide the generation and evaluation of data in the subsequent successive risk assessment steps. Problem formulation also requires the development of methods – through a conceptual model and analysis plan – that will help to direct the risk characterisation and to produce information that will be relevant for decision-making. Information considered in problem formulation includes published scientific literature, expert opinions, research data and relevant data derived from molecular, compositional and agronomic/phenotypic analyses performed during GM plant development. If the level and

quality of the available information is high, then the risk assessment can reduce the number of hypotheses that need to be tested for risk characterisation. It is obvious that the testing of those policy-related hypotheses should be as rigorous and objective as any hypothesis testing in any other branch of science (Raybould 2007).

Balancing environmental risks and opportunities

The debate on the environmental risks of GM plants in Europe has intersected with a wider debate about the applicability of genetic engineering to sustainable agriculture, blurring distinctions between environmental, agricultural and socio-economic issues (Myhr and Traavik 2003; Mayer and Stirling 2004; Johnson et al. 2007; Devos et al. 2008). As discussions about environmental safety become framed more broadly, a more holistic approach to assessing and addressing risks has been suggested, so that potential environmental benefits are assessed as well as the environmental risks.

Like environmental harms, environmental benefits are also determined by values. A strict interpretation of environmental benefits might be the opposite of environmental harm; thus, if a reduction in some attribute is regarded as harmful, an increase in that attribute would be seen as beneficial. Other definitions might broaden "environmental" benefits to consider socio-economic factors that probably would not be considered when drawing up definitions of environmental harm.

However, because the main objective of the risk-based legislation regulating the use of GMOs in Europe is to ensure a high level of environmental protection, it focuses on the assessment of risks only and does not explicitly consider whether GM plants fulfil wider socio-economic and ecological aspirations (Devos et al. 2008) and meet other policy objectives (Tait and Barker 2011; Raybould and Poppy 2012; Masip et al. 2013). In effect, protection is seen as preserving a baseline condition; it is not seen as improving the environment. In other words, a missed opportunity to improve the environment is not regarded as an environmental risk. Ideally, however, new technologies should be assessed not only on their risks to human and animal health and the environment, but also on their potential benefits (i.e., opportunities). Tait and Barker (2011) went a step 282 further by advocating the need to make decisions about the acceptability of new technologies in the context of other risks as well as the costs of not using these technologies. Considering potential environmental benefits as well as risks may enable an interpretation of the precautionary principle that is explicitly linked to the ideal of sustainable development (Deblonde and du Jardin 2005) through a proper evaluation of the options

available for decision-making and estimation of the costs and benefits associated with possible decisions as well as the costs of inaction (Tait 2001; Eckerstorfer and Gaugitsch 2013).

Several scientific risk assessment bodies have suggested that adoption of a specific method of crop management (whether GM or conventional) should be based on consideration of the overall environmental consequences and that such consideration will require a broader and more balanced legislative oversight in the EU (ACRE 2007; EFSA 2008; COGEM 2009). At the EFSA colloquium concerning challenges and approaches for the environmental risk assessment of GM plants, for example, the discussion group concerned with broadening the scope of the environmental risk assessment recommended that a paradigm shift would be required to change from risk assessment as it is currently practiced to a more sophisticated assessment that balances risks and benefits (EFSA, 2008). The EFSA report further stated that the status quo, in which risk assessment is interpreted very narrowly in terms of adverse effects, is not sustainable, suggesting that decision support tools should be build that enable risk assessors to better consider effects of whole farming systems. However, fundamental policy concepts such as sustainability could only be considered in the environmental risk assessment for particular products if risk managers define clear policy objectives for sustainable agriculture.

Apart from the fact that it is difficult to integrate a risk/opportunity or a sustainability assessment in the regulatory environmental risk assessment of a product, such an assessment should not be restricted to the approval of single GM plants. It is important to recognise that the above assessment ought to be conducted for classes of products, not for particular products. In addition, risks from GM plants should be evaluated against the same criteria as risks from any other agricultural management practice. Sanvido et al. (2012) argued that future political and legislative processes in Europe should attempt to harmonise the different legal frameworks regulating agricultural technologies, such as the ones regulating the environmental risk assessment of pesticides and GM plants. Discussions on how socio-economic considerations could be implemented to further develop the revised EU legislative framework are continuing (EC 2011; Greiter et al. 2011; Lusser et al. 2012; Eckerstorfer and Gaugitsch 2013). The European Commission recently set up a working group, consisting of experts from EU Member States, to explore the methodological framework for a socio-economic assessment of GMOs, and also established the European Socio-Economic Bureau at the Joint Research Centre.

In addition to considering the potential benefits of new technologies, those who analyse risks should also recognise that the real choice is not between GM plants and their associated farm

management practices that are perceived as inherently risky and conventionally-bred plants and traditional pest and weed management that are perceived as completely safe. Both types of cropping systems have positive and negative environmental effects (Sanvido et al. 2007, 2012).

Expanding participation in risk governance

Several authors have recommended the establishment of wider knowledge assessment to ensure responsible innovation (Gaskell et al. 2005; Stirling 2008), claiming that wider societal considerations should play a role in the production of policy goals, defining what represents environmental harm and the communication of the risk decision (Johnson et al. 2007). Theoretically, this allows more democratic and thus more legitimate decision-making and enables risk managers to consider divergent interpretations of scientific shortcomings and of the underlying values and ideals held by different actors. Such a 'rational orchestration' of public voices has in fact already been undertaken in Europe, through consensus conferences and citizen panels in science evaluation (Stirling 2008), with no discernable impact on the level of conflict over GM plant development.

Whether the consideration of public opinion should be further enhanced and which of the science communication models is best suited to legitimise decisions on agricultural biotechnology in Europe has still to be determined. Two critical factors are the practicability and the usefulness of the different models for regulatory decision-making. The usefulness of public participatory events, for example, should be critically discussed (Genus and Coles 2005; Hagendijk and Irwin 2006; Irwin 2006; Tait 2009). Several observers have noted that these participatory events rarely allow the examination of wider societal and ethical concerns, and are of secondary importance to the much debated demand for a cultural change in key decision-making and scientific institutions (Mayer and Stirling 2002; Jensen et al. 2003; Madsen and Sandøe 2005). It may also reflect the difficulty to fully align narrow and stringent legal frameworks with complex and often fluctuating ethical concerns (Karlsson 2003; Devos et al. 2008). It thus remains a challenge to take the wide range of societal concerns seriously in both decision-making and risk communication.

CONCLUSION

We have suggested ways in which the basis for regulatory decision-making about the cultivation of GM plants may be clarified. In particular, we point out that science serves to help us realise objectives based on our values. Science does not determine what those values ought to be.

An important conclusion from the distinction between values and science is that scientists wishing to advocate policies for or against the use of GM plants should state whether their advocacy is based on a preference for certain policy objectives based on their values. Scientists have as much right as anyone else to argue for their values. However, scientists ought not to claim that their scientific expertise gives special weight to those values.

Once policy objectives are clear and agreed, scientific expertise can determine 352 the particular policy instruments best suited to achieving those objectives. Without clarification of the values underlying policy objectives, Sarewitz (2007) argued that opposing scientific views about policy instruments are often proxies for the conflicting values.

The case of agricultural biotechnology in Europe shows that regulatory decision-making is blocked primarily by disputes over values, which are not sufficiently recognised and deliberated as such. Bringing the value disputes concealed by, and embodied in, science and also in advocacy to the foreground of decision-making may be a crucial factor in turning the controversy about agricultural biotechnology in Europe into successful democratic action (Sarewitz 2004). Risk managers may no longer be in a position to hide behind the scientific controversy claiming they are waiting for the results of the next round of research if they decide not to act. Instead, they must explain allegiance to inaction in terms of their own values and interests, and become accountable for their decisions (Sarewitz 2007). Openly debating value differences will allow policy objectives to be agreed upon properly and allow science to fulfil its legitimate role of designing policy instruments, including regulatory decisions, to achieve those objectives.

It should also be critically discussed whether the consideration of public concerns in decision-making would lead to enhanced public trust in agricultural biotechnology. In theory, public opinion may show risk managers relevant societal concerns that would merit to be specifically addressed. On the other hand, it could be likely that these concerns are mainly hypothetical and reflect an artificial situation that could change if clear benefits of GM plants would become obvious.

Recognising and openly debating differences about values will not remove controversy about the cultivation of GM plants. However, by revealing what is truly in dispute, debates about values will clarify decision-making criteria.

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DISCLAIMER

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